UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FEDERAL TRADE COMMISSION, STATE OF ILLINOIS, and STATE OF MINNESOTA, *Plaintiffs,* v. GTCR, LLC, GTCR BC Holdings, LLC, and SURMODICS, INC., *Defendants*.	Case No. 1:25-cv-02391 District Judge Jeffrey I. Cummings Magistrate Judge Gabriel Fuentes

OPPOSED MOTION OF GTCR BC HOLDINGS, LLC TO COMPEL UNITED STATES FOOD AND DRUG ADMINISTRATION TO COMPLY WITH SUBPOENA

Pursuant to Federal Rule of Civil Procedure 45(d)(2)(B)(i), Defendant GTCR BC Holdings, LLC ("BC Holdings") moves to compel the United States Food and Drug Administration ("FDA") to comply with its subpoena obligation to produce medical device approval applications filed from January 2010 to the present for devices that may use a lubricious coating within any product codes listed in Appendix A to the Subpoena.

BC Holdings and the FDA have agreed to a proposed deadline of July 3, 2025, for the FDA's opposition, with no reply brief.

INTRODUCTION

The executive branch of the federal government, via the Federal Trade Commission ("FTC"), brought this suit to block BC Holdings' acquisition of Surmodics, Inc. (the "Proposed Acquisition"). Dkt. 1. At the same time, the executive branch of the federal government, via the FDA, is withholding

materials that BC Holdings needs to defend itself. The Court should reject the FDA's manufactured vague complaints about burden, find that purported confidentiality concerns are already addressed by the protective order, and order it to comply with BC Holdings' subpoena (the "Subpoena").

The FTC alleges that BC Holdings' purchase of Surmodics will substantially lessen competition in an alleged market for "outsourced hydrophilic coatings," while simultaneously noting FDA approval is required to change a coating on a medical device. Dkt. 67-1 ¶¶ 86-87. Given its unique regulatory role for medical devices, the FDA is the only complete source of information to measure the merging parties' position on new device projects in the FTC's alleged market and how that has evolved over time. Indeed, it is surprising that the FTC chose to bring this action, including articulating a market definition, without first assembling FDA submissions to understand the marketplace and the parties' relative positions in providing lubricious coatings to medical device manufacturers seeking FDA approval. BC Holdings' only alternative to receiving FDA applications from the FDA would be to collect these applications from hundreds of device manufacturers, an insurmountable burden in the timeframe required for the preliminary injunction hearing.

But the FDA refuses to budge. After seven weeks of outreach to find a path forward, the agency has not produced a single document—citing confidentiality concerns that are already addressed by the protective order in place and burden complaints that are based only on the FDA's own self-imposed and incorrect view that it needs to manually review records for confidentiality. Left with no other choice, BC Holdings brings this motion to compel.

REQUEST FOR RELIEF

BC Holdings requests that the Court grant this motion and require the FDA to produce, within fourteen (14) days, the 510(k), PMA, and De Novo submissions for all devices that may use a lubricious coating within any product codes provided in Appendix A to the Subpoena from January

1, 2010 until now (Ex. A). At a minimum, BC Holdings requests that the Court compel the FDA to provide access, within seven (7) days, to its personnel with knowledge of how such submissions are maintained so that a minimally burdensome procedure for access can be determined to retrieve them.

BACKGROUND

On April 14, 2025, BC Holdings served the Subpoena on the FDA seeking documents and data that medical device manufacturers submitted to the FDA that relate to lubricious medical device coatings (the "Requests"). *See* Ex. A. Specifically, the Requests pertain to 510(k), PMA, and De Novo applications seeking FDA approval for the commercialization of medical devices using lubricious coatings, limited to 81 of the FDA's 1,700-plus medical device classifications or "product code[s]."[1] These documents will allow BC Holdings to understand the lubricious coating market and the merging parties' positions in that market.

In a communication to the FDA after serving the Subpoena, BC Holdings expressed its "hope to engage with [the FDA] to learn about how the FDA stores information," its goal "to minimize the burden of this process as much as possible," and highlighted the time-sensitive nature of the request. Ex. B at 2. The FDA declined to meet until April 22, when it sent BC Holdings a Rule 45 letter with its objections. *See* Ex. C at 1. BC Holdings responded the same day requesting a meeting for that day or the next. *See* Ex. D. The FDA agreed to its first meet and confer one week later, and the parties undertook the meet and confers listed below.

Date	Discussion Topics[2]
April 29, 2025 at 12:00 PM	▪ FDA claimed that scope of the Subpoena is beyond FDA capability, and requested two weeks to confer with medical device experts.

[1] *See* United States Food and Drug Administration, *Classify Your Medical Device*, (Feb. 7, 2020), https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device.
[2] This table establishes BC Holdings' compliance with Local Rule 37.2.

	▪ BC Holdings agreed to provide FDA two weeks to track down the relevant locations of the requested submissions. ▪ BC Holdings explained that it provided a limited set of 81 out of the 1700-plus device codes to find 510(k), PMA, and De Novo submissions related to medical devices that might use lubricious coatings. ▪ FDA agreed these submissions would likely describe coatings. ▪ FDA acknowledged that it had been able to make productions before under a "strong protective order," but that it would have to consult with the disclosure office.
May 16, 2025 at 11:00 AM	▪ FDA claimed that Rule 45 subpoenas are subject to the same confidentiality restrictions as FOIA requests for public disclosure. ▪ FDA claimed it would have to individually review FDA submissions and apply redactions, which could take a decade. ▪ BC Holdings explained that this was a Rule 45 subpoena subject to a protective order, which FDA acknowledged was helpful. ▪ FDA stated the need to individually notify every medical device applicant whose submission was being disclosed. ▪ BC Holdings suggested that FDA rely on its own notice by publication rule; FDA said that solution was novel and would need to be investigated. ▪ BC Holdings confirmed it would accept the filings by product code with no analysis, review, or modification and would conduct all review itself. ▪ FDA suggested BC Holdings subpoena all medical device applicants directly, and BC Holdings explained this would be impossibly burdensome and non-exhaustive of materials that FDA already has in its custody.
May 28, 2025 at 1:30 PM	▪ BC Holdings reiterated urgency given the fact discovery deadline and noted that the Subpoena does not seek deliberative process information. ▪ FDA agreed the protective order is robust, but claimed that its own *Touhy* rules prohibit it from disclosing the submissions. ▪ FDA explained a database exists with the requested submissions, reducing the burden of production.

	▪ BC Holdings offered a search strategy for the submission database, but FDA rejected it and declined to provide any narrowing alternative. ▪ FDA confirmed it has not yet attempted to identify the responsive materials and does not plan to. ▪ BC Holdings confirmed to FDA that they had reached an impasse and would be moving to compel.

Having failed to solicit productive engagement from the FDA, BC Holdings notified the FDA it would move to compel. After asking the FDA to discuss areas of agreement, disagreement, and potential limiting of the scope of the Requests, the FDA responded that it "is not in a position to locate, retrieve, and review records responsive to this request" and suggested, again, that BC Holdings "reach out directly to the owner[s] of the information." Ex. E at 3. The FDA shared no meaningful path to providing the requested documents and did not offer conference with the issue-area experts in the applications. The FDA has yet to produce a single document.

The FDA's principal objection is that the Subpoena is "overly broad and unduly burdensome" under Rule 45(d), and that its *Touhy* regulations prevent it from "public" disclosure of the requested submissions. *See* 21 C.F.R. § 20.61. Under those regulations, the FDA requires itself to treat "[a]ny request for records [], whether it be by letter or by a subpoena," as a FOIA request "whether or not the Freedom of Information Act is mentioned." 21 C.F.R. §§ 20.2, 20.23; *see* 5 U.S.C. § 301 (allows federal agencies to establish *Touhy* regulations governing when they will disclose information or make employees available for depositions). The FDA stated that FOIA Exemption 4 requires it to manually review each page of responsive records to redact "trade secrets as well as commercial or financial information that is obtained from a person that is either privileged or confidential"—which it maintained would impose years of burden. 32 C.F.R. § 1662.21. The FDA also objected that the

Subpoena "may" seek documents implicating deliberative process and that, if so, it would be required to notify all submitters.

As part of the meet-and-confer process, BC Holdings responded as follows to the FDA's concerns: (i) in the context of a subpoena, the regulations do not require the FDA to manually review materials that are exempt from FOIA disclosure; (ii) materials produced under a subpoena are subject to the Protective Order entered by the Court, which would protect their confidentiality; (iii) BC Holdings does not seek documents implicating the FDA's deliberative process; and (iv) the FDA does not have to individually notify all relevant submitters. *See* Ex. E at 6. Despite these efforts, the FDA declined to reach accord.

To date, the FDA has not produced a single document responsive to, or given details on how its data is stored to narrow, the Subpoena.

ARGUMENT

I. The Subpoena Requests Relevant Materials Proportional to the Needs of the Case.

The Court should compel the FDA to produce materials in compliance with the Subpoena. *See Watts v. SEC*, 482 F.3d 501, 508 (D.C. Cir. 2007) (Rule 45 motion to compel is the proper vehicle to compel an agency to respond to a subpoena). The "general criterion for judicial review of subpoenas" is whether the subpoena "is reasonable in the circumstances." *Gaines v. Chicago Bd. of Educ.*, 2022 WL 1292248, at *2 (N.D. Ill. Apr. 29, 2022) (quoting *McKevitt v. Pallasch*, 339 F.3d 530, 533 (7th Cir. 2003)). "The burden rests upon the objecting party to show why a particular discovery request is improper." *McDaniel v. Loyola Univ. Med. Ctr.*, 2015 WL 13901027, at *2 (N.D. Ill. June 23, 2015) (citations omitted).[3] The limits and breadth of discovery imposed by Rule 26 are

[3] This Court has jurisdiction to hear this Motion under 15 U.S.C. § 23, which provides that in United States government-party actions, "subpoenas for witnesses who are required to attend a court of the United States in any judicial district in any [civil case] arising under the antitrust laws may run into any other district." *See* Dkt.

applicable to non-party discovery under Rule 45. *See Hankins v. Alpha Kappa Sorority, Inc.*, 619 F. Supp. 3d 828, 833 (N.D. Ill. 2021).

Relevance and proportionality guide the scope of discovery under Rule 26. *See Deal Genius, LLC v. O2COOL, LLC*, 682 F. Supp. 3d 727, 732 (N.D. Ill. 2023). A discovery request "should be considered relevant if there is any possibility that the information sought may be relevant to the subject matter of the action." *Meyer v. S. Pac. Lines*, 199 F.R.D. 610, 611 (N.D. Ill. 2001) (citation omitted). Proportionality is governed by the importance of the issues at stake, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. *See* Fed. R. Civ. P. 26(b)(1); *Bankers Life and Cas. Co. v. Alshoubaki*, 2016 WL 11940391, at *8 (N.D. Ill. June 27, 2016).

The Subpoena seeks from the FDA materials that are directly probative of the FTC's allegations—specifically, whether the FTC's alleged "outsourced hydrophilic coatings" market is sensible under the antitrust laws and what position the merging parties hold in a sensibly constructed medical device coatings market. The FDA is the *only* complete source of information—medical device approval applications for certain devices that may use a lubricious coating—directly pertinent to that issue. Identifying suppliers of the lubricious coatings in FDA applications is central to establishing how to properly determine a sensible lubricious coatings market under the antitrust laws, BC Holdings' and Surmodics' position in that market, and whether the proposed acquisition will create anticompetitive effects. *See United States v. UnitedHealth Grp. Inc.*, 630 F. Supp. 3d 118, 130 (D.D.C. 2022) ("[T]he government can establish its *prima facie* case simply by showing that the

71 at 13 (providing for nationwide service of process for Rule 45 subpoenas under 15 U.S.C. § 23); *FTC v. Kroger Co.*, 2024 WL 3400098, at *3 (D. Or. July 12, 2024) ("15 U.S.C. § 23 confers nationwide enforcement power over subpoenas issued pursuant to that provision."); *FTC v. Meta Platforms, Inc.*, 2025 WL 985530, at *3 (D.D.C. Apr. 2, 2025) (same).

merger would produce a firm controlling an undue percentage share of the relevant market[.]") (internal quotes omitted). The FTC itself recognizes the FDA's unique position as a source of crucial information, alleging that "[t]he FDA regulates the production, development, testing, manufacture, marketing, and promotion of medical devices in the United States." Dkt. 67-1 ¶¶ 38, 45.

The information that BC Holdings seeks—a subset of medical device applications in the FDA's possession related to lubricious coatings—is plainly relevant to show that the FTC's alleged product market (restricted to "outsourced hydrophilic coatings") fails and that its alleged market shares are inaccurate. The FTC further alleges post-merger anticompetitive effects, including harm to competition for lubricious coatings customers. Dkt. 66 ¶¶ 62–70. The FDA controls the database that reflects the market reality of competition for lubricious coatings for the relevant medical devices.

The Requests are also proportional to BC Holdings' need, with the benefits to BC Holdings in presenting its defense far outweighing any burden on the FDA to pull these submissions. Fed. R. Civ. P. 26(b)(1); *see Bankers Life and Cas. Co.*, 2016 WL 11940391, at *6 (concluding "that the relevance and probative value of the information sought substantially outweigh[ed] any undescribed burden."); *BankDirect Cap. Fin., LLC v. Cap. Premium Fin., Inc.*, 326 F.R.D. 171, 175 (N.D. Ill. 2018) ("Proportionality, like other concepts, requires a common sense and experiential assessment."). BC Holdings cannot access the relevant information elsewhere because the only authoritative, complete compilation is in the FDA's sole possession, custody, and control.

II. The FDA Has Failed to Articulate Valid Confidentiality or Undue Burden Concerns for Resisting the Subpoena.

The confidentiality and burden objections the FDA asserts here are meritless and have been rejected in the past. In *SEC v. Selden*, 445 F. Supp. 2d 11 (D.D.C. 2006), the defendant in an action brought by the Securities Exchange Commission ("SEC") sought relevant materials via subpoena from the FDA. *Id.* at 11–12. The FDA moved to quash, arguing that the subpoena requests did not

comply with its *Touhy* regulations, created undue burden, targeted trade secrets and confidential commercial information, and sought documents exempt from public disclosure by the deliberative process privilege and personal privacy regulations. *Id.* at 13 n.3. But the FDA had not actually processed the subpoena as a FOIA request pursuant to its *Touhy* regulations, so the court held that it had no way of assessing burden. *See id.* at 14 (explaining the court was "unable to assess the FDA's [burden argument]" because it "has not yet taken the appropriate administrative action on these requests under its regulations"). Accordingly, the Court denied the FDA's motion to quash and ordered it to "respond to [the defendant's] subpoenas pursuant to its *Touhy* regulations." *Id*.

As in *Selden*, the FDA's burden of complying with the subpoenas is "speculative," as the FDA has refused to even locate the records. *See* Ex. E at 3. *Selden* ordered the FDA to proceed "with dispatch" and not place the "subpoena request at the back of the FOIA que." *Id.* at 14 n.7 (noting the "FDA must engage Selden's request, and formulate a response, with dispatch"). BC Holdings seeks the same relief here. *See also Albany Molecular Rsch., Inc. v. Schloemer*, 274 F.R.D. 22, 24 (D.D.C. 2011) (denying motion to quash subpoena to the FDA based on confidentiality concerns).

A. Nothing in the FDA's *Touhy* Regulations Requires the FDA to Redact Material that is Exempted from FOIA in Responding to a Rule 45 Subpoena.

As noted, the FDA's own *Touhy* regulations require it to treat "[a]ny request for records [], whether it be by letter or by a subpoena," as a FOIA request, "whether or not the Freedom of Information Act is mentioned." 21 C.F.R. §§ 20.2, 20.23. These regulations provide the process by which the FDA must comply with requests for production.

But settled law holds when the FDA—or any federal agency—is served with a valid subpoena, it may not withhold production simply because the requested materials are, under its *Touhy* regulations, exempt from public disclosure under FOIA. *See Houston Bus. J., Inc. v. Office of the Comptroller of the Currency*, 86 F.3d 1208, 1212 (D.C. Cir. 1996) ("[N]either the Federal

Housekeeping Statute nor the *Touhy* decision authorizes a federal agency to withhold documents from a federal court"). Indeed, while the Federal Housekeeping Statute, 5 U.S.C. § 301, requires the FDA to promulgate *Touhy* regulations, the statute simply establishes a process to manage the process of production, not to control the substance of materials produced. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979) ("The 1958 amendment to § 301 was the product of congressional concern that agencies were invoking § 301 as a source of authority to withhold information from the public. … [A]n amendment … added the last sentence to § 301, [] specifically states that this section does not authorize withholding information from the public.") (citation and internal quotations omitted); *Exxon Shipping Co. v. U.S. Dept. of Interior*, 34 F.3d 774, 777 (9th Cir. 1994) (holding that § 301 "does not, by its own force, authorize federal agency heads to withhold evidence sought under a valid federal court subpoena").

B. Even if Information Requested by the Subpoena Were Confidential Under FDA's *Touhy* Process, the Protective Order Obviates Confidentiality Concerns.

Even if the Requests' sought documents properly considered confidential under FOIA and thus deemed confidential per the FDA's own *Touhy* process, the Protective Order in this case would protect the confidentiality of those materials. In fact, the FDA's own objection letter acknowledges that an adequate protective order could address its confidentiality concerns and obviate the attendant burdens of review and redactions it would "*otherwise*" need to undertake. Ex. C at 3 (emphasis added). And the FDA's *Touhy* regulations confirm that the FOIA exemptions need not apply to material revealed in court proceedings point, stating: "Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration (FDA) administrative proceedings … *or court proceedings*, where data or information are relevant." 21 C.F.R. § 20.86 (emphasis added). These are precisely the court proceedings contemplated by the regulations, and the Protective Order here "reduce[s] disclosure to the minimum necessary under the circumstances." 21

CFR § 20.86. Producing the limited set of FDA submissions sought by the Requests, without redactions under the Protective Order, would achieve exactly this end.

Yet, in an effort to avoid compliance with the Subpoena, the FDA asserts that it must manually review every page of responsive material to make FOIA exemption decisions. But the Court has already entered the Protective Order. Dkt. 61. This is significant, as courts regularly compel non-party subpoena recipients to produce relevant materials when a protective order would protect the confidentiality of those materials. *See, e.g.*, *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, 2014 WL 5465401, at *2 (N.D. Ill. Oct. 27, 2014) (a protective order limiting disclosure to outside counsel and retained experts sufficiently addressed non-party competitor's concerns regarding disclosure of its confidential information); *Meridian Labs., Inc. v. Oncogenerix USA, Inc*., 2021 WL 4768256, at *4 (N.D. Ill. 2021) (Cummings, J.) (subpoena recipient's "concerns in handing over responsive documents to a company that it alleges is developing a competing product" would be addressed by amending protective order to allow only for outside counsel access).

The Protective Order more than fits the bill. The Court entered the Protective Order "[f]or the purpose of protecting the interests of the parties and third parties … against the improper use and disclosure of confidential information submitted or produced in connection with" the case. Dkt. 61 at 1. The Protective Order permits "any third parties, in complying with … subpoenas in this Litigation" to "designate any responsive Document or portion thereof as Confidential Material," with access restricted only to outside counsel and retained experts. *Id*. at 2-3. This designation protects exactly the kind of materials with which the FDA is concerned: "any trade secret or competitively sensitive research, analysis, technical, financial, development, or commercial information that has not been released into the public domain." *Id.* at 1. And the FDA knows this protection exists—BC Holdings'

counsel confirmed during the meet-and-confer that any materials the FDA designates "Confidential Material" cannot and will not be disclosed to Defendants or their employees.

The FDA asserts that the Protective Order does not obviate the need to review and redact produced materials. That assertion is incorrect, as courts regularly hold that protective orders—even those less robust than the Protective Order here—are sufficient to address such concerns. *See Buergofol GmbH v. Omega Liner Co., Inc.*, 2025 WL 859894, at *6-7 (D.S.D. Mar. 19, 2025); *Albany Molecular Rsch.*, 274 F.R.D. at 24 ("The existence of a protective order weighs against quashing the subpoena on commercial information grounds because the protective order is designed to protect and prevent public disclosure of confidential and sensitive business information, like that potentially at issue here."); *Feature Films Servs., Inc. v. Arts & Ent. Network Corp.*, 1991 WL 290677, at *1 (N.D. Ill. Jan. 13, 1991) ("[T]he law squarely rejects the defendants [sic] refusal to produce discovery because of confidentiality concerns in the face of a protective order.") (citing *Truswal Sys. Corp. v. Hydro-Air Eng'g, Inc.*, 813 F.2d 1207, 1211 (Fed. Cir. 1987)). Specifically, in *Buergofol*, the court held that U.S. Customs and Border Protection's refusal to produce documents related to "trade secrets" and "confidential commercial information" was unreasonable because it failed to consider whether the protective order in the case would "adequately protect disclosed information from improper, competitive uses." 2025 WL 859894, at *6-7; *see also Grupo Petrotemex, S.A. De C.V. v. Polymetrix AG*, 2018 WL 5307823, at *7 (D. Minn. Oct. 26, 2018) (same). Similarly, in *Albany Molecular Research*, the Court held that a protective order allowing parties to designate documents as confidential or "even as attorneys' eyes only" ensured that the documents would be "fully protected from disclosure or use outside the ongoing litigation." 274 F.R.D. at 26-27 (denying motion to quash non-party subpoena to the FDA).

C. The FDA Failed to Articulate Grounds for Concluding that the Subpoena Imposes an Undue Burden.

An objecting party that asserts undue burden must demonstrate undue burden. *See Guster-Hines v. McDonald's USA, LLC*, 2024 WL 4242009, at *3 (N.D. Ill. May 21, 2024) ("[O]ne claiming undue burden must do more than intone the phrase.") (citation omitted). The FDA refused to meaningfully investigate the burden imposed by the Subpoena. *See supra* at 3–6. The FDA further admits that it has not attempted to "locate, retrieve, [or] review records responsive to this request," despite acknowledging during the meet-and-confer that the pertinent device applications are maintained together in a database. *See* Ex. E at 3; *see also EEOC v. Aerotek, Inc.*, 815 F.3d 328, 334 (7th Cir. 2016) ("The actual process of producing the data imposes little burden [when] the company maintains a database containing all of the requested information."). Rather, the FDA says, without elaboration, that it "simply does not have the resources to take on such a burden" to respond to the Subpoena. Ex. E at 2. This alone is grounds to reject the FDA's claim of undue burden. *See Selden*, 445 F. Supp. 2d at 12 (in ordering production, noting where "the FDA has not yet processed [the] subpoena[], the court cannot assess whether any document production would be unduly burdensome"). The FDA to date has otherwise provided only general epithets about burden, with perfunctory concerns regarding notice to third parties and protecting deliberative process that are irrelevant.

i. The FDA can provide notice by publication, instead of individually, to third parties on their production if required.

The FDA asserts that before producing the requested medical device applications, it must notify each applicant individually. *See* Ex. E at 2, 6. That is wrong, as FDA regulations provide a less burdensome alternative—notice by publication. *See* 21 C.F.R. § 20.61(e)(1) ("If the Food and Drug Administration must notify a large number of submitters, notification may be done by posting or publishing a notice in a place where the submitters are reasonably likely to become aware of it.").

When BC Holdings presented it with that alternative, the FDA claimed that using notice of publication would be "novel" and that it would have to investigate that notice method—which, to BC Holdings' knowledge, the FDA has not yet done. To the extent notice is required, the FDA should be able to easily effectuate a global notice. *See, e.g.*, *N.Y. Times Co. v. FDA*, 529 F. Supp. 3d 260, 287 (S.D.N.Y. 2021) ("Of course, such notices [on agency websites] or communications [with submitters] could also explicitly notify submitters of the agency's intention to publicly disseminate the information.") (citation omitted).

ii. FDA failed to articulate a burden concern regarding deliberative process since BC Holdings confirmed the Subpoena does not seek it.

The FDA further asserts that, "[b]ased on FDA's experience with similar requests," it "expect[s]" that "some" responsive documents "may" contain materials reflecting pre-decisional deliberative process. Ex. C at 3. But BC Holdings has affirmatively disclaimed any interest in material concerning deliberative process. *See* Ex. E at 6. Indeed, BC Holdings seeks *only* materials submitted *by* medical device applicants *to* the FDA. By definition, the requested materials could not possibly contain the FDA's internal processes and deliberations.

CONCLUSION

For the foregoing reasons, BC Holdings respectfully requests that the Court order the FDA to produce the materials requested by the Subpoena within 14 days.

Dated: June 18, 2025

Daniel P. Culley (*pro hac vice*)
D. Bruce Hoffman (*pro hac vice*)
Blair West Matthews (*pro hac vice*)
Gabriel J. Lazarus (*pro hac vice*)
CLEARY GOTTLIEB STEEN & HAMILTON LLP
2112 Pennsylvania Ave., NW
Washington, D.C. 20037
202-974-1500
dculley@cgsh.com
bhoffman@cgsh.com

bmatthews@cgsh.com
glazarus@cgsh.com

Heather S. Nyong'o (*pro hac vice*)
CLEARY GOTTLIEB STEEN & HAMILTON LLP
650 California St.
San Francisco, CA 94108
415-796-4400
hnyongo@cgsh.com

Matthew Yelovich (*pro hac vice*)
CLEARY GOTTLIEB STEEN & HAMILTON LLP
1841 Mill Page Road
Palo Alto, CA 94304
650-815-4152
myelovich@cgsh.com

Miranda Herzog (*pro hac vice*)
CLEARY GOTTLIEB STEEN & HAMILTON LLP
One Liberty Plaza
New York, NY 10006
212-225-2152
mherzog@cgsh.com

Sean M. Berkowitz
Gary Feinerman
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
312-876-7700
sean.berkowitz@lw.com
gary.feinerman@lw.com

Alfred Pfeiffer
Kelly S. Fayne (*pro hac vice pending*)
LATHAM & WATKINS LLP
505 Montgomery Street, Suite 2000
San Francisco, CA 94111
415-391-0600
al.pfeiffer@lw.com
kelly.fayne@lw.com

Ian Conner (*pro hac vice forthcoming*)
Amanda P. Reeves (*pro hac vice pending*)

LATHAM & WATKINS LLP
555 Eleventh Street, NW
Washington, DC 20004
202-637-2200
ian.conner@lw.com
amanda.reeves@lw.com

Counsel for GTCR BC Holdings, LLC

CERTIFICATE OF SERVICE

I hereby certify that, on June 18, 2025, I caused a copy of the foregoing document to be served on counsel listed below via email, all other parties are served by ECF through the court's filing system:

FDA Info Share Team
(FDAInfoShare@fda.hhs.gov)
Kelsey Schaefer (kelsey.schaefer@fda.hhs.gov)
Valerie Raedy (valerie.raedy@usdoj.gov)

Dated: June 18, 2025

Daniel P. Culley

Counsel for GTCR BC Holdings, LLC